

Art Unit: 1614  
Serial No: 09/072,504

### **REMARKS**

Claims 1-25 were examined, with claims 1, 9, 18 and 23 being independent. By present amendment, claims 1, 4, 5, 6, 9, 18 and 23 were amended to more particularly point out and distinctly claim what Applicant regards as the invention. Thus, after entry of this Amendment, claims 1-25 will be pending in the application.

The Applicant appreciates the courtesies extended by the Examiner in the telephone interview conducted on December 15, 2004.

### **Rejection of claims 1-8 for lack of utility**

Claims 1-8 were rejected under 35 U.S.C. §101 because the Patent Office stated that the claimed invention was not supported by either a credible asserted utility or a well-established utility. To support its position, the Patent Office cited a 1974 article by the instant inventor for the proposition that attempts to eliminate dental hypersensitivity have "not been uniformly successful for various reasons." As a result, the Patent Office concluded that preparation of a composition to "prevent" dentinal hypersensitivity was not realistically achievable given the state of the art at this time. A 24-year old statement by the instant inventor, whose work has concentrated in this area, cannot be considered to be determinative of whether the inventor has in fact conceived of a solution to the problem in the 24 years between the article and the filing of the instant application. The state of the art in any area changes, and the state of the art in this area is driven at least in part by the instant inventor's contributions to the art. Nonetheless, in the interest of furthering prosecution of the application, and without acceding to the correctness of the Patent Office's position, Applicant has amended claim 1 to replace "preventing" with "inhibiting."

Withdrawal of the rejection is respectfully requested.

Art Unit: 1614  
Serial No: 09/072,504

**Rejection of claims 1-25 as indefinite**

Claims 1-25 were rejected under 35 U.S.C. §112, second paragraph, as indefinite. In the interest of furthering prosecution of the application, and without acceding to the correctness of the Patent Office's position, Applicant has amended claims 1, 4, 5, 6, 9, 18 and 23, to recite "by weight based on the total weight of the composition." Withdrawal of the rejection is respectfully requested.

Claims 11 and 12 were also rejected under 112 paragraph two, as indefinite because of use of the term "high viscosity." The Patent Office stated that "high viscosity" is a relative term which renders the claim indefinite, and the fact the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprized of the scope of the invention.

The Applicant respectfully traverses the rejection.

One of ordinary skill in the art would understand the term "high viscosity matrix material" to be a high viscosity matrix material having a viscosity comparable to that of carboxypolymethylene. The specification as filed on page 6, lines 13 through 14, states that the composition may comprise a high viscosity matrix material, such as carboxypolymethylene (Carbopol). Thus, this specification does not limit the high viscosity matrix material to carboxypolymethylene, and one of ordinary skill in the art would understand that materials having a viscosity comparable to that of carboxypolymethylene also could be used as a matrix material in the composition.

Withdrawal of the rejection is respectfully requested.

**Anticipation of Claims 1-7, 9-12, 14-16, 23 by Jensen**

Claims 1-7, 9-12, 14-16, 23 and 24 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,306,370 to Jensen et al. (Jensen), with claims 1, 9 and 23 being independent.

The Applicant respectfully traverses the rejection.

A Declaration under 37 C.F.R. § 1.131 is submitted herewith showing a conception date prior to the filing date of the earliest application to which the Jensen patent claims priority.

Art Unit: 1614  
Serial No: 09/072,504

Accordingly, Applicant requests withdrawal of the rejection of claims 1, 9 and 23, and any claims dependent thereon, as anticipated by Jensen under 35 U.S.C. §102(e).

**Obviousness of Claims 18-21 over Jensen**

Claims 18-21 were rejected under 35 U.S.C. §103(a) as unpatentable over Jensen, with claim 18 being independent.

The Applicant respectfully traverses the rejection.

A Declaration under 37 C.F.R. § 1.131 is submitted herewith showing a conception date prior to the filing date of the earliest application to which the Jensen patent claims priority.

Accordingly, Applicant requests withdrawal of the rejection of claim 18 and any claims dependent thereon as obvious over Jensen under 35 U.S.C. §103(a).

**Obviousness of Claims 8, 13, 17, 22 and 25 over Jensen in view of Norfleet**

Claims 8, 13, 17, 22 and 25 were rejected under 35 U.S.C. §103(a) as unpatentable over Jensen in view of U.S. Patent No. 5,486,350 to Norfleet et al. (Norfleet), with all claims being dependent.

The Applicant respectfully traverses the rejection.

A Declaration under 37 C.F.R. § 1.131 is submitted herewith showing a conception date prior to the filing date of the earliest application to which the Jensen patent claims priority.

Accordingly, Applicant requests withdrawal of the rejection of Claims 8, 13, 17, 22 and 25, and any claims dependent thereon, as obvious over Jensen in view of Norfleet under 35 U.S.C. §103(a).

**Obviousness of Claims 1-17 and 23-25 over Fischer in view of Norfleet**

Claims 1-17 and 23-25 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,098,303 to Fischer in view of Norfleet, with claims 1, 9 and 23 being independent.

Art Unit: 1614  
Serial No: 09/072,504

The Patent Office acknowledged that Fischer fails to disclose a potassium-containing compound to reduce tooth hypersensitivity. The Patent Office also acknowledged that Norfleet fails to disclose peroxide-compound bleaching agents in sufficient detail to be an anticipatory reference. The Patent Office stated that Norfleet discloses that potassium nitrate, potassium citrate and potassium oxalate are equivalent, and then concluded that it would have been obvious to have included 1 to 15% of potassium nitrate, potassium citrate or potassium oxalate in the tooth bleaching gel of Fischer, motivated by the desire to inhibit the development of dental hypersensitivity as taught by Norfleet.

The Applicant respectfully traverses the rejection.

Fischer is deficient as a reference because it fails to disclose: (1) from 1% to 35% by weight of a potassium-containing compound, as in Claims 1 and 23; or (2) 5-7% by weight of a potassium-containing compound, as in Claim 9.

Norfleet is deficient as a reference because it fails to disclose: (1) from 1% to 35% by weight of a potassium-containing compound, as in Claims 1 and 23; or (2) a composition that is not a dentifrice and does not contain an abrasive, as in Claims 1, 9 and 23. Norfleet is additionally deficient as a reference because it teaches away from using desensitizers in concentrations of greater than 15%.

As an initial matter, the Patent Office must provide some motivation to make a modification, which can be found in the references, or in the prior art. It is not enough to simply show that a modification can be made - that is impermissible hindsight. Moreover, it is not proper to pick selected portions of a reference in disregard for the teaching of the reference as a whole.

For example, the Patent Office stated that Fischer recognized that tooth bleaching processes induced hypersensitivity. While that is true, the Patent Office has disregarded the teachings of Fischer as a whole in this regard. Specifically, Fischer did recognize that tooth bleaching caused sensitivity, especially at sites where dentin was exposed, and Fischer even proposed a solution to the problem - covering the dentin with a layer of dentin bonding agent or sealant. (Fischer, col. 9, ll. 1-8). But, even though Fischer recognized the problem, it failed to provide any teaching or suggestion

Art Unit: 1614  
Serial No: 09/072,504

for another way to overcome the problem e.g. by adding a desensitizer to its compositions to inhibit sensitivity, or the advantages of doing so. In fact, Fischer was altogether silent on this point. Therefore, the only solution proposed by Fischer was very mechanical - providing a barrier to the bleach so that it never contacted the exposed areas of dentin. The solution proposed by Fischer was also limited, because it addressed only sensitivity resulting from the bleaching composition contacting the exposed areas of dentin, and did not address all areas contacted by the bleaching composition. Thus, the Patent Office selected only a specific teaching of Fischer, in disregard of the whole. The fact is that Fischer's entire invention was related to compositions, and yet he did not even think to include anything in the compositions to desensitize. Therefore, Fischer does not provide the motivation to make the combination proposed by the Patent Office.

Similarly, the Patent Office stated that Norfleet taught that desensitizers could be used in non-toothpaste gels. While this is correct, a closer reading of the section of Norfleet cited by the Patent Office shows that Norfleet provides a laundry list of oral preparations "not intended for brushing onto the teeth...such as mouth rinses, antiseptic solutions, chewing gums, tooth treating agents...and even dental floss and dental tape." (Norfleet at col. 7, ll. 1-6). This statement: (1) does not mention a bleaching composition: and (2) does not disclose compositions that remain on teeth for extended periods, such as bleaching compositions. It appears that the Patent Office has taken the position that bleaching compositions are included in this list, because Norfleet did not specifically exclude them from this laundry list. Assuming, for the sake of argument, that such an interpretation is correct, then the most that can be said is that Norfleet may suggest adding a desensitizer to an oral preparation "not intended for brushing onto the teeth...such as mouth rinses, antiseptic solutions, chewing gums, tooth treating agents...and even dental floss and dental tape." But Norfleet does not suggest adding a desensitizer to a bleaching composition. This distinction is important, as will be discussed in greater detail below.

Also, the Patent Office stated that Norfleet briefly mentions "per-compound" bleaching agents in a laundry list of potential additives. Again, while this statement may be correct, it is taken out of context, because the Patent Office has implied that Norfleet discloses non-abrasive

Art Unit: 1614  
Serial No: 09/072,504

desensitizing compositions, which disregards the teachings of Norfleet as a whole in this regard. At the outset of the specification, Norfleet stated that "[t]his invention relates to desensitizing anti-tartar dentifrices...."(Norfleet, col. 1, ll. 9-10). After several pages devoted entirely to describing the composition and materials used in the dentifrices, Norfleet disclosed a laundry list of components that can be contained in its dentifrice compositions, including the "bleaching agents and tooth whiteners, such as per-compounds" noted by the Patent Office. (Norfleet, at col. 6, ll. 35-53). This reference to bleaching agents is the only reference that occurs in Norfleet. In fact, other than the briefest mention of other compositions "not intended for brushing onto the teeth," as discussed above, which does not mention bleaching compositions, the specification of Norfleet before and after the "bleaching" laundry list was devoted exclusively to dentifrice compositions which, by definition, contain an abrasive. Therefore, Norfleet may suggest adding a peroxide composition to its dentifrice to form a bleaching toothpaste. But Norfleet does not suggest adding a peroxide to its dentifrice, and then removing the abrasive from the dentifrice to obtain an abrasive-free desensitizing composition. This distinction is also important, as will be discussed in greater detail below.

In addition, as noted above, Norfleet teaches away from using desensitizers in concentrations of greater than 15%. Norfleet discloses concentrations of 2-10% of the desensitizer are typical, but that exceeding 15% will cause "taste considerations." (Norfleet at col.7, ll. 59-62 and 65-67). In view of this teaching, then why would anyone be motivated to add greater than 15% of a desensitizer to any composition? Thus, in addition to being deficient as a reference, Norfleet additionally teaches away from compositions that include desensitizers in concentrations of greater than 15%. This teaching away takes on more importance when taken with the well known fact that bleaching compositions remain on teeth for extended periods of time. For example, if dentifrices contact teeth for only brief periods of time when brushing, and concentrations of greater than 15% cause a taste problem, then certainly such a concentration in a bleaching composition that remains on teeth for extended periods would only exacerbate the problem i.e. provide a prolonged the unpleasant taste experience. Moreover, even though Norfleet discloses that concentrations exceeding 15% compromised the taste of its dentifrices, which are used only for a short period of time, one can infer

Art Unit: 1614  
Serial No: 09/072,504

that lower concentrations for extended periods of time also might suffer from the same taste problem. Therefore, increasing the concentration of desensitizer to greater than 15% again would only exacerbate the problem further. Consequently, Norfleet teaches away from using concentrations of greater than 15% in compositions, and in fact teaches that lower concentrations are better for taste reasons.

Despite the foregoing, assuming for the sake of argument that one of ordinary skill in the art at the time the invention was made was motivated to combine Fischer and Norfleet, the present invention still would not be obtained. Based on the alternative interpretations of Norfleet, if one assumed that Norfleet disclosed a non-abrasive desensitizer, then one possible result of the combination of Fischer and Norfleet would be a bleaching composition containing a poly phosphate anti-tartaric as an essential ingredient, and a desensitizer with a concentration of potassium-containing compound of less than 15%. Thus, in order to arrive at the presently claimed invention, the combination of Fischer and Norfleet would require further modification to increase the potassium-containing compounds to exceed 15 wt.% - 35 wt.%. For the reasons discussed above, there is simply no motivation to make such a modification.

If one assumed that Norfleet disclosed a desensitizing dentifrice, then another possible result of the combination of Fischer and Norfleet would be a bleaching composition containing an abrasive, a poly phosphate anti-tartaric as an essential ingredient, and a desensitizer with a concentration of potassium-containing compound of less than 15%. Thus, in order to arrive at the presently claimed invention, the combination of Fischer and Norfleet would require further modification to: (1) remove of the abrasive; and/or (2) increase the potassium-containing compounds to exceed 15 wt.% - 35 wt.%. Removing an abrasive from a dentifrice renders it unuseable for its intended purpose - to provide mechanical scrubbing of teeth. Moreover, Norfleet states that the anti-tartaric is an essential component. Removing the anti-tartaric component from the composition also renders it unuseable for its intended purpose - to prevent tartar formation. Again assuming for the sake of argument that one of ordinary skill in the art was motivated to make such a modification, i.e. decided that for some reason it was beneficial to include a dentifrice in a composition that was intended to remain on the

Art Unit: 1614  
Serial No: 09/072,504

teeth for an extended period of time, and for perhaps many repetitions of the same, still further modification of the composition would be required because the taste of the tooth pain inhibitor would render the dentifrice unusable for its intended purpose.

Clearly, in combining Fischer and Norfleet, the Patent Office has simply used hindsight recognition based on the present invention and has simply picked one item from Norfleet - the desensitizer - and has attempted to show that adding it to desensitizer to the bleaching composition of Fischer will provide the presently claimed invention, but the combination does not result in the presently claimed invention, and there is no motivation to make the combination.

Claims 1, 9 and 23 are therefore patentable over Fischer and Norfleet, alone or in combination. The claims that depend from claims 1, 9 and 23 directly or indirectly are patentable for at least the same reasons. Withdrawal of the rejection is respectfully requested.

**Obviousness of Claims 18-22 over Fischer in view of Norfleet,  
and further in view of Velluci**

Claims 18-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fischer in view of Norfleet, and further in view of U.S. Patent No. 4,294,894 to Velluci, with claim 18 being independent.

The Patent Office's position with respect to Fischer and Norfleet is discussed above. The Patent Office acknowledges that the combined teachings of Fischer and Norfleet failed to disclose compositions containing 30 to 40% glycerin and 32 to 35% propylene glycol. The Patent Office cited Velluci only for demonstration of the general state of the art, and stated that Velluci discloses that it is well known to use propylene glycol as a carrier in all care compositions, either alone or in admixture with glycerin. The Patent Office acknowledges that Velluci fails to disclose their particular compositions recited in the claims. Based on the foregoing, the Patent Office has concluded that it would have been obvious to have used propylene glycol as a partial replacement for glycerin in the compositions suggested by the combined teachings of the primary and secondary references, Fischer and Norfleet. The Patent Office states that the motivation for doing so is the



Art Unit: 1614  
Serial No: 09/072,504

desire to modify particular compositions to tailor them to have particular optimal and/or desired physical characteristics, since such modification is routine in the art as taught by Velluci allegedly. The Patent Office then concludes that having arrived at such a combination, that it would have been obvious to have operated within the percentage range of 20 to 70% provided by Fischer, selecting mixtures having weight percentages of glycerin and propylene glycol following within the recited claimed values, motivated by the desire to optimize performance for a particular given formulation.

Applicant respectfully traverses the rejection.

The deficiencies of Fischer and Norfleet, alone or in combination, are discussed above. In addition, Norfleet fails to disclose any particular concentration of peroxide-based bleach that could be included in its dentifrice composition.

Velluci fails to cure the deficiencies of the combination of Fischer and Norfleet. Velluci discloses a transparent medicated toothpaste i.e. dentifrice, and does not provide any disclosure, teaching or suggestion to remove the abrasive from the composition, or to add a bleaching composition or a desensitizer to the composition.

The bleaching gel of claim 18 comprises from 5 to 10% by weight carbamide peroxide and from 3 to 5% by weight a potassium-containing compound that is not a dentifrice and does not contain an abrasive.

Fischer, Norfleet and Velluci, alone or in combination, fail to disclose, teach or suggest a composition comprising a peroxide containing compound and a potassium-containing compound, that is not a dentifrice and does not contain an abrasive.

Claim 18 is therefore patentable over Fischer, Norfleet and Velluci, alone or in combination. The claims that depend from claim 18 directly or indirectly are patentable for at least the same reasons. Withdrawal of the rejection is respectfully requested.

Art Unit: 1614  
Serial No: 09/072,504

**CONCLUSION**

In view of the foregoing amendments and remarks, the Applicant respectfully submits that all of the claims pending in the above-identified application are in condition for allowance, and a notice to that effect is earnestly solicited. If the Patent Office does not consider the present application to be in condition for allowance, then the Applicant hereby requests a telephone or personal interview to facilitate the resolution of any remaining matters. Applicant's attorney may be contacted by telephone at the number indicated below to schedule such an interview.

The U.S. Patent and Trademark Office is authorized to charge any additional fees incurred as a result of the filing hereof or credit any overpayment to our deposit account 06-1130.

Respectfully submitted,  
HODOSH, MILTON, Applicant

Dated: January 28, 2005

By: 

Michele J. Young, Reg. No. 48,299  
Applicant's Attorney  
CANTOR COLBURN, LLP  
55 Griffin Road South  
Bloomfield, CT 06002  
Telephone: (860) 286-2929  
Facsimile : (860) 286-0115